CHAPTER 11
SECTION 7.1

CERTIFICATION OF ORGAN TRANSPLANT CENTERS

ISSUE DATE: June 20, 1988
AUTHORITY: 32 CFR 199.6(b)(4)(ii) and (b)(4)(iii)

I. POLICY

A. Certifying Authority. The TRICARE contractor is the certifying authority for applications for status as a TRICARE-authorized institutional provider for liver, heart, combined heart-kidney, combination liver-kidney, pancreas-alone, lung, heart-lung, and small intestine (SI) within its region. Medicare is the approving authority for kidney transplant centers.

B. General Certification Requirements. To obtain TRICARE certification as an organ transplant center, the center must have:

1. An active solid organ transplantation program.

2. Participation in a donor organ procurement program and network.

3. An interdisciplinary body to determine the suitability of candidates for transplantation on an equitable basis.

4. An anesthesia team that is available at all time.

5. A nursing service team trained in the hemodynamic support of the patient and in managing immunosuppressed patients.

6. Pathology and immunology resources that are available for studying and reporting the pathological responses to transplantation.

7. Evidence that the center safeguards the rights and privacy of patients.

8. Continual compliance with state transplantation laws and regulations, if any.

9. Legal counsel familiar with transplantation laws and regulations.

C. The continued compliance of a certified transplantation center must be verified by the contractor no less than every 24 months.

D. Reporting Requirements. The transplant center must report to the TRICARE certifying authority any decrease in actuarial survival rates below the actuarial survival rate established by TRICARE for initial facility certification.

E. Liver Transplantation Centers. TRICARE shall provide coverage for liver transplantation procedures performed only by experienced transplant surgeons at centers complying with the provisions outlined above in paragraph I.B. and the following criteria or status as a TRICARE-certified liver transplantation center may be granted based upon Medicare certification as a liver transplant center.

1. The transplant center must:

a. Have staff board eligible or board certified physicians and other experts in the fields of hepatology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, and anesthesiology to complement a qualified transplantation team.

b. Have a transplant surgeon who is specifically trained for liver grafting and who can assemble and train a team to function successfully whenever a donor liver is available.

c. Have at least a 50 percent one year actuarial survival rate for 10 cases as calculated using the Kaplan-Meier product limit method. A 50 percent one-year actuarial survival rate for all subsequent liver transplantations must be maintained for continued TRICARE approval.

F. Heart Transplantation Centers. TRICARE shall provide coverage for heart transplantation procedures performed only by experienced transplant surgeons at centers complying with provisions outlined above in paragraph I.B. and the following criteria or status as a TRICARE-certified heart transplantation center may be granted based upon Medicare certification as a heart transplantation center.

1. The transplant center must:

a. Have experts in the fields of cardiology, cardiovascular surgery, anesthesiology, immunology, infectious disease, nursing, social services, and organ procurement to complement the transplant team.

b. Have an active cardiovascular medical and surgical program as evidenced by a minimum of 500 cardiac catherterizations and coronary arteriograms and 250 open heart procedures per year.

c. Have an established heart transplantation program with documented evidence of 12 or more heart transplants in each of the three consecutive preceding 12-month periods prior to the date of application (a total of 36 or more heart transplantation procedures).

d. Demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years for patients who have had heart transplants since January 1, 1982 at that facility. The Kaplan-Meier product limit method shall be used to calculate actuarial survival.

2. TRICARE approval will lapse if either the number of heart transplants falls below 8 in 12 months or if the one-year actuarial survival rate falls below 60 percent for a consecutive 24-month period.

G. Lung Transplantation. TRICARE shall provide coverage for lung transplantation procedures performed only by experienced transplant surgeons at centers complying with the provisions outlined above in paragraph I.B. and the following criteria or status as a TRICARE-certified lung transplantation center may be granted based upon Medicare certification as a lung transplantation center.

1. The center must have:

a. Experts in the fields of cardiology, cardiovascular surgery, pulmonary disease, anesthesiology, immunology, infectious disease, nursing, social services, and organ procurement to complement the transplant team.

b. Performed lung (single and/or double) transplantation in at least 10 patients within the 12 months prior to application and in at least an additional 10 patients prior thereto.

c. Demonstrated Kaplan-Meier actuarial survival rates of no less than 65 percent at one-year post-transplantation for patients who have undergone lung transplantation at the center since January 1, 1987.

H. Heart-Lung and Lung Transplantation. TRICARE shall provide coverage for heart-lung transplantation procedures performed only by experienced transplant surgeons at centers complying with the provisions outlined above in paragraph I.B. and meeting either the heart or lung transplantation criteria or performed in a Medicare-certified heart, lung or heart-lung transplant center.

I. Small Intestine (SI), Combined Small Intestine-Liver (SI/L), and Multivisceral Transplantation. TRICARE shall provide coverage for SI, SI/L, and multivisceral transplantation procedures performed only by experienced transplant surgeons at centers complying with the provisions outlined above in paragraph I.B. and meeting the following criterion or status as a TRICARE-certified transplant center may be granted based upon Medicare certification as a small intestine transplant center:

Perform 10 SI, SI/L, or multivisceral transplants with a documented Kaplan-Meier actuarial survival rate of no less than 65 percent at one-year.

J. Simultaneous Pancreas-Kidney and Pancreas-After-Kidney Transplantation. TRICARE shall provide coverage for simultaneous pancreas-kidney transplantation procedures performed only by experienced transplant surgeons at Medicare-approved renal transplant centers complying with the provisions outlined above in paragraph I.B. and meeting the following criteria:

1. Performed SPK or PAK transplantation in at least 20 patients within 12 months prior to application.

2. Achieve a documented Kaplan-Meier actuarial patient survival rate of no less than 91 percent at one-year.

K. Pancreas-Transplantation-Alone. TRICARE shall provide coverage for pancreas-transplantation alone performed only by experienced transplant surgeons at centers complying with the provisions outlined above in paragraphs B. through D. and meeting the following criteria:

1. Performed whole pancreas transplantation in at least 15 patients within 12 months prior to application.

2. Achieve a documented Kaplan-Meier actuarial patient survival rate of no less than 90% at one year.

L. Combined Liver-Kidney Transplantation. If the facility is certified as a TRICARE (or Medicare) certified liver transplant center, the facility may be considered to be a certified center to perform combined liver-kidney transplants.

M. Kidney Transplantation. Kidney transplants must be performed at a Medicare-approved transplant center.

N. Combined Heart-Kidney Transplantation. Combined heart-kidney transplants must be performed at a center certified by TRICARE or Medicare for heart transplantation and Medicare-approved for renal transplantation.

O. Organ Transplant Consortia. TRICARE shall approve individual pediatric organ transplant centers which meet the General Certification Requirements outlined above in paragraph B., and would otherwise qualify as a TRICARE-certified transplantation center by using the combined experience and survival date of a consortium of which a single transplant team rotates among member hospitals for purposes of meeting the certification requirements outlined in paragraphs E. through N. above, for heart, heart-lung, liver, liver-kidney, heart-kidney, small intestine, small intestine-liver, multivisceral, pancreas, pancreas-kidney when:

1. The consortium hospitals are under common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally-constituted medical research institute;

2. The consortium hospitals share resources by using the same personnel or services in their transplant programs. The individual physician members of the transplant team practice in all of the hospitals;

3. The same organ procurement organization, immunology, and tissue typing services are used by all the hospitals; and

4. The hospital submits its individual and combined experience and survival data to the TRICARE authorizing authority; and

5. If one of the hospitals is a pediatric transplant program, in addition to the requirements previously listed the following apply:

a. Although pediatric surgeons and pathologists are not required to practice the adult hospital and vice versa, it can be documented that they otherwise function as members of the transplant team.

b. The facility must have other solid organ transplant program(s) that meet TRICARE criteria for certification based on actuarial survival rates and experience.

c. The surgeon responsible for the transplant is commonly involved in the type of surgery (i.e., related to hepatology, cardiology and pulmonary medicine) with children of the age and size in whom the transplant is being performed; and

d. If the program involves heart transplant, the facility must have an active pediatric cardiovascular medical and surgical program with a minimum of 150 cardiac catheterizations performed per year on patients in the pediatric range. A surgical case load of 200 operations per year should be performed in combined adult and pediatric programs: of these, at least 100 operations per year (three of four should use extracorporeal circulation) should be on pediatric patients. In programs serving only a pediatric population, at least 100 cardiac procedures (three of four should use extracorporeal circulation) should be performed per year.

P. Calculation of Survival Rates for Transplantation. Each facility seeking TRICARE certification as a transplantation center must calculate survival rates using the Kaplan-Meier (product-limit) technique utilizing the definitions and rules below. Each applicant facility must identify its Kaplan-Meier actuarial survival percentage at one year. Each applicant facility must also submit calculations to support the reported survival percentage.

1. Each applicant facility will report all transplantation experience from its inception at the facility.

2. TRICARE recognizes the team experience gained in retransplantation. Therefore, retransplantation experience must be reported and calculated in the same manner as first transplantation experience.

3. All experience and survival rates must be reported as of a point in time that is no more than 90 days prior to the submission of the application for TRICARE certification. That date is referred to as the fiducial date.

4. Calculations assume survival only to (and censoring on) the date of last ascertained survival.

5. Patients who are not thought to be dead are considered "lost to follow-up" if they were:

a. Operated more than 120 days before the fiducial date, but have no ascertained survival within 60 days of the fiducial date; or

b. Operated from 61 to 120 days before the fiducial date, but ascertained survival is less than 60 days from date of transplant; or

c. Operated within 60 days of the fiducial date, but not ascertained to have survived as of the fiducial date.

6. Survival must be calculated with the assumption that each patient in the "lost to follow-up" category died on or one day after the date of last ascertained survival.

7. Clearly defined and well justified secondary or alternate treatment of "lost to follow-up" may also be submitted, but primary attention will be given to the results using definitions and procedures specified above.

8. These specified definitions and procedures use a simpler format but are identical to those published by CMS (Federal Register, Volume 52, Number 85; April 6, 1987; pages 10947-8).

9. Facilities seeking certification for lung and/or heart-lung transplantation must report all lung and heart-lung transplantation experience. When facility experience is reported and the actuarial survival is calculated, lung and heart-lung transplantation experience must be combined to arrive at a single one-year survival percentage.

Q. Revocation of Provider Status. In the event a transplant center's certified provider status is revoked, the certifying authority shall provide a copy of the initial determination terminating the provider to:

1. The transplant center affected.

2. The Regional Director of the TRICARE region.

3. The TRICARE Management Activity-Aurora, Program Integrity Branch.

R. Patient Selection. The patient must meet the requirements criteria for the applicable transplant as outlined in each individual transplant policy.

II. EXCLUSIONS

Facility certification is not required for transplants other than those listed in paragraph I.A.

III. EFFECTIVE DATE

For those centers meeting the certification requirements, approval is effective on the date the application is signed by the applicant or the date the contractor determines that the facility met TRICARE certification requirements.

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